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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,472	09/08/2003	Tracee Eidenschink	S63.2H-11273-US01	2675

490 7590 06/16/2005

VIDAS, ARRETT & STEINKRAUS, P.A.  
6109 BLUE CIRCLE DRIVE  
SUITE 2000  
MINNETONKA, MN 55343-9185

EXAMINER
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SIRMONS, KEVIN C

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/657,472	Applicant(s) EIDENSCHINK ET AL.	
	Examiner Kevin C. Sirmons	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2005.  
 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 19-25 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☒ Claim(s) 2,3,6-11,13 and 14 is/are allowed.  
 6) ☒ Claim(s) 1, 4, 5, 12 and 19-25 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al U.S. Pat. No. 6,099,497.

Adams discloses a catheter, the catheter comprising a catheter shaft, the catheter shaft defining a first guide wire lumen (figs. 14d, 17 and 18); a rotatable sheath (156), the rotatable sheath being disposed about at least a portion of the catheter shaft and rotatable thereabout, the rotatable sheath having a length substantially less than that of the catheter shaft (figs. 14d, 17 and 18); and a secondary guide wire housing (136), the secondary guide wire housing defining a secondary guide wire lumen (136), at least a first distal portion of the guide wire housing being engaged to at least a first proximal portion of the rotatable sheath (figs. 14d, 17 and 18); as to claims 4-5, (see above figs.).

Claims 1, 4, 5 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Stone et al U.S. Pat. No. 5,843,027.

Stone discloses a catheter assembly (figs. 1-5); a rotatable sheath (28 and/or 40).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams.

Adams discloses the assembly substantially as claimed except for various types of materials, which the sheath can be constructed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the sheath from various materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Additionally, Adams teaches that the stent may be any suitable and commercially available materials.

Furthermore, Applicant has not disclosed that the various materials provides an advantage, is used for a particular purpose, or solves a stated problem. Basically, applicant lacks criticality for the various materials.

***Allowable Subject Matter***

Claims 2, 3, 6-11, 13 and 14 are allowable over the prior art of record.

### ***Response to Arguments***

Applicant's arguments filed 4/11/05 have been fully considered but they are not persuasive.

First, the word sheath has very little if any structure, therefore, a sheath can be anything that is disposed about at least a portion of the catheter. Secondly, rotatable is clearly functional. Any mechanism that is capable of rotating around the shaft of the catheter meets the requirements. Furthermore, the sheaths of Adam and Stone are fully capable of performing the function as set forth in the claim. Lastly, in Adam, the sheath is rotatable before it enters the body (i.e. before it is crimped) and it is also rotatable once the sheath has been expanded. The rejection is maintained!

Basically, applicant's remaining rejected claims have very little structure and a plethora of functional language. It is suggested that applicant place more structure in the claim to get it allowed.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin C. Sirmons whose telephone number is 571-272-4965. The examiner can normally be reached on Monday-Friday 6:30-4:00 ALT FRI.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kevin C. Sirmons  
Primary Examiner  
Art Unit 3763  
6/13/05

